



Atty. Dkt. No. 067286-0276

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicants: James C. KENNEDY et al.

Title: PHOTOCHEMOTHERAPEUTIC METHOD  
USING 5-AMINO LEVULINIC ACID AND  
PRECURSORS THEREOF

Appl. No.: 10/605,824

Filing Date: 10/29/2003

Examiner: Unassigned

Art Unit: 1617

**INFORMATION DISCLOSURE STATEMENT**  
**UNDER 37 CFR §1.56**

Mail Stop PATENT APPLICATION  
Commissioner for Patents  
PO Box 1450  
Alexandria, Virginia 22313-1450

Sir:

Applicants submit herewith on Form PTO/SB/08 a listing of the documents cited by or submitted to the U.S. PTO in parent application Serial No. 09/816,329, filed 03/26/2001. As provided in 37 CFR §1.98(d), copies of the documents are not being provided since they were previously submitted to the United States Patent & Trademark Office in the above-identified parent application.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

**TIMING OF THE DISCLOSURE**

The listed documents are being submitted in compliance with 37 CFR §1.97(b), before the mailing date of the first Office Action on the merits.

**RELEVANCE OF EACH DOCUMENT**

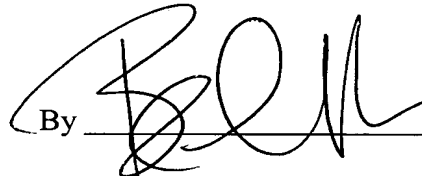
The relevance of the listed documents is explained in the parent application.

Applicants respectfully request that any listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

Respectfully submitted,

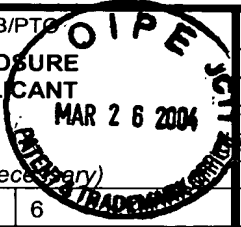
Date 26 March 2004

By 

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			Application Number	10/605,824	
			Filing Date	10/29/2003	
			First Named Inventor	James C. Kennedy	
			Group Art Unit	1617	
			Examiner Name	Unassigned	
Sheet	1	of	6	Attorney Docket Number	067286-0276

**U.S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			
	A1	5,211,938		KENNEDY et al.	05/93	
	A2	5,219,878		RINGUET et al.	06/93	
	A3	5,163,990		REBEIZ	11/92	
	A4	5,200,427		REBEIZ et al.	04/93	
	A5	5,079,262		KENNEDY et al.	01/92	
	A6	5,234,940		KENNEDY et al.	08/93	
	A7	4,772,681		FUKUDA et al.	09/88	
	A8	4,977,177		BOMMER et al.	12/90	
	A9	5,004,811		BOMMER et al.	04/91	
	A10	5,127,938		REBEIZ	07/92	
	A11	5,422,093		KENNEDY et al.	06/95	
	A12	4,932,934		DOUGHERTY et al.	06/90	
	A13	5,425,728		TANKOVICH	06/95	
	A14	5,226,907		TANKOVICH	07/93	
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	A16	5,484,803		RICHTER	01/96	
	A17	5,955,490		KENNEDY, et al.	09/99	
	A18	5,705,518		RICHTER et al.	06/98	

**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Documents	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
	A19	EP	0 233 701			08/87		
	A20	WO	95/07077			03/95		

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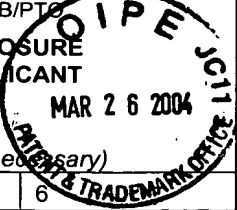
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	A21	WO	93/08715			05/93		
	A22	WO	91/01727			02/91		
	A23	WO	95/31189			11/23/95		
	A24	WO	94/06424			3/31/94		
	A25	WO	95/05813			3/2/95		
	A26	WO	93/20810			10/28/93		
	A27	WO	94/12239			6/9/94		

NON PATENT LITERATURE DOCUMENTS					
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	A28	BOEHNCKE, et al., Treatment of Psoriasis by Topical Photodynamic Therapy with Polychromatic Light, <i>The Lancet</i> , 343:801, March 1994			
	A29	FUKUDA et al., Photodynamic Action of Endogenously synthesized Porphyrins from Aminolevulinic, <i>Int. J. Biochem.</i> , 25:10; 1395-98, 1993			
	A30	LOH et al., Endogenous Porphyrin Distribution-Induced by 5-Aminolaevulinic Acid. . . , <i>J. Photochem. Photobiol.</i> , 20:47-54, 1993			
	A31	VAN DER VEEN et al., In Vivo Fluorescence Kinetics and Photodynamic Therapy Using 5-Aminolaevulinic, <i>Br. J. Cancer</i> , 70:867-72, 1994			
	A32	GRANT et al., Photodynamic Therapy of Normal Rat Arteries After Photosensitisation Using . . . , <i>Br. J. Cancer</i> , 70:72-78, 1994			
	A33	German Abstract No. A78035910, "Investigation and Therapy In Dermatology With Dye Lasers", ANDERS et al., pp. 772, (1977)			
	A34	QIAN et al., "A Comparison Of Different Photosensitizing Dyes With Respect To Uptake C3H-Tumors and Tissues Of Mice", <i>Cancer Letts.</i> , Vol. 36:1-10, (1987)			
	A35	MALIK et al., "New Trends In Photobiology (Invited Review) Bactericidal Effects Of Photoactivated Porphyrins - An Alternative Approach To Antimicrobial Drugs", <i>Journal of Photochemistry and Photobiology</i> , Vol. 5:281-293, (1990)			

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	A36	KENNEDY et al., "Topical Photodynamic Therapy For Cancers Of The Skin", <i>Canadian Dermatology Association Journal</i> , Vol. 5, No. 3, pp. 45-47, (1991)		
	A37	BICKERS et al., "Biosynthesis of Porphyrins in Mammalian Skin And In The Skin Of Porphyric Patients", <i>The Journal Investigative Dermatology</i> , Vol. 68:5-9, (1977)		
	A38	MALIK et al., "5-Aminolevulinic Acid Stimulation Of Porphyrin And Hemoglobin Synthesis by Uninduced Friend Erythroleukemic Cells", <i>Cell Differentiation</i> , Vol. 8:223-233, (1979)		
	A39	MALIK et al., "Destruction of Erythroleukaemic Cells By Photoactivation Of Endogenous Porphyrins", <i>Br. J. Cancer</i> , Vol. 56:589-595, (1987)		
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	A41	MALIK et al., "Regulation Of Hemoglobin Synthesis, Iron Metabolism, And Maturation Of Friend Leukemic Cells By 5-Amino Levulinic Acid and Hemin", <i>Differentiation</i> , Vol. 13:71-79, (1979)		
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	A43	HANANIA et al., "The Effect of EDTA And Serum On Endogenous Porphyrin Accumulation And Photodynamic Sensitization Of Human K562 Leukemic Cells", <i>Cancer Letters</i> , Vol. 65:127-131, (1992)		
	A44	SIMA et al., "Experimental Porphyric Neuropathy: A Preliminary Report", <i>Canada J. Neurol. Sci.</i> , Vol. 8, No. 2, pp. 105-114, (1981)		
	A45	KENNEDY et al., "Endogenous Protoporphyrin IX, A Clinically Useful Photosensitizer For Photodynamic Therapy", <i>J. Photochem. Photobiol. B: Biol.</i> , Vol. 14:275-292, (1992)		
	A46	SHIZHENG et al., "Endogenous Porphyrins In Murine Skin And Transplanted PAM-212 Squamous Cell Carcinoma Tissues After Injection of $\delta$ -Aminolevulinic Acid", <i>Chinese Medical Journal</i> , Vol. 108(4):286-290, (1995)		
	A47	YANG et al., "Treatment With 5-Aminolevulinic Acid And Photoactivating Light Causes Destruction Of Preimplantation Mouse Embryos", <i>Fertility and Sterility</i> , Vol. 63(5):1088-1093, (1995)		
	A48	HUA et al., "Effectiveness of $\delta$ -Aminolevulinic Acid-Induced Protoporphyrin As A Photosensitizer - For Photodynamic Therapy In Vivo", <i>Cancer Research</i> , Vol. 55:1723-1731, (1995)		
	A49	ASH et al., "New Drugs And Future Developments In Photodynamic Therapy", <i>Eur. J. Cancer</i> , Vol. 29A(12):1781-1783, (1993)		

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	A50	KOENIG et al., "In Vivo Photoproduct Formation During PDT With ALA-Induced Endogenous Porphyrins", <i>J. Photochem. Photobiol. B: Biol.</i> , Vol. 18:287-290, (1993)		
	A51	VAN HILLEGERBERG et al., "Current Status of Photodynamic Therapy In Oncology", <i>Drugs</i> , Vol. 48(4):510-527, (1994)		
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	A53	WOLF et al., "Photodynamic Therapy for Mycosis Fungoides After Topical Photosensitization With 5-Aminolevulinic Acid", <i>Journal of the American Academy of Dermatology</i> , Vol. 31:678-680, (1994)		
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	A55	YANG et al., "Intrauterine 5-Aminolevulinic Acid Induces Selective Fluorescence And Photodynamic Ablation Of The Rat Endometrium", <i>Photochemistry And Photobiology</i> , Vol. 57(5):803-807, (1993)		
	A56	GRANT et al., "Photodynamic Therapy of Oral Cancer: Photosensitisation With Systemic Aminolaevulinic Acid", <i>The Lancet</i> , Vol. 342:147-148, (1993)		
	A57	LOH et al., "Oral Versus Intravenous Administration Of 5-Aminolaevulinic Acid For Photodynamic Therapy", <i>Br. J. Cancer</i> , Vol. 68:41-51, (1993)		
	A58	CHARLESWORTH et al., "The Use of 5-Aminolevulinic Acid (ALA) In Photodynamic Therapy (PDT)", <i>News And Views</i> , Vol. 18:99-100, (1993)		
	A59	KENNEDY, "Photochemotherapy - Clinical Aspects", Department of Oncology and Pathology, Photosensitisation. Edited by G. Moreno et al., pp. 453-463, (1988)		
	A60	KENNEDY, "Photodynamic Therapy With Endogenous Protoporphyrin IX: Basic Principles And Present Clinical Experience", <i>Journal of Photochemistry and Photobiology, B: Biology</i> , Vol. 6:143-148, (1990)		
	A61	DENNIS et al., "Protection of NIH 3T3 Cells From Infection By Trypomastigotes And Sphaeromastigotes Of <i>J. Trypanosoma Cruzi</i> , Telahuen Strain, By Porphyrins In The Presence And Absence of Light (630 and 690 NM)", <i>Parasitol.</i> , Vol. 75(6):970-976, (1989)		

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	A62	BERLIN et al., "Normal Pathways, Studied With The Aid of N", <i>The Metabolism of <math>\delta</math>-Aminolaevulic Acid</i> , Vol.64:80-99,(1956)		
	A63	BRAULT et al., "Fundamental Aspects In Tumor Photochemotherapy: Interactions Of Porphyrins With Membrane Model Systems And Cells", <i>Biochimie</i> , Vol. 68:913-921, (1986)		
	A64	DIVARIS et al., "Phototoxic Damage To Sebaceous Glands And Hair Follicles Of Mice After Systemic Journal Administration of 5-Aminolevulinic Acid Correlates With Localized Protoporphyrin IX Fluorescence", <i>American of Pathology</i> , Vol. 136(4):891-897, (1990)		
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	A67	KORELL et al., "Einsatz der Photodynamischen Lasertherapie in der Gynaekologie", <i>Gynaekol Geburtshilfliche Rundsch</i> , Vol. 35:90-97, (1995)		
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	A69	SZEIMIES et al., "Topische Photodynamische Therapie In Der Behandlung Oberflaechlicher Hauttumoren", <i>Hautarzt</i> , Vol. 46:315-318, (1995)		
	A70	WOLF et al., "Photodynamic Therapy With 5-Aminolevulinic Acid:A Promising Concept For The Treatment of Cutaneous Tumors", <i>Dermatology</i> , Vol. 190:183-185, (1995)		
	A71	YANG, et al., "Evidence of Lasting Functional Destruction Of The Rat Endometrium After 5-Aminolevulinic Acid Induced Photodynamic Ablation: Prevention of Implantation", <i>Am. J. Obstet. Gynecol.</i> , Vol. 168(3):995-1001, (1993)		
	A72	WOLF, et al., "Topical Photodynamic Therapy With Endogenous Porphyrins After Application of 5-Aminolevulinic Acid", <i>J. Am. Acad. Dermatol.</i> , Vol. 28:17-21 (1993)		
	A73	GOFF et al., "Effects Of Photodynamic Therapy With Topical Application of 5-Aminolevulinic Acid On Normal Skin of Hairless Guinea Pigs", <i>J. Photochem. Photobiol. B: Biol.</i> , Vol. 15:239-251, (1992)		

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Sheet 6 of 6	Attorney Docket Number	067286-0276	

## NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>5</sup>
	A74	PENG et al., "Distribution And Photosensitizing Efficiency Of Porphyrins Induced by Application Of Exogenous 5-Aminolevulinic Acid In Mice Bearing Mammary Carcinoma", <i>Int. J. Cancer</i> , Vol. 52:433-443, (1992)	
	A75	SUROLIA et al., "De Novo Biosynthesis Of Heme Offers A New Chemotherapeutic Target In The Human Malarial Parasite", <i>Biochemical And Biophysical Research Communications</i> , Vol. 187(2):744-750, (1992)	
	A76	VAN HILLEGERSBERG et al., "Selective Accumulation Of Endogenously Produced Porphyrins In A Liver Metastasis Model in Rates", <i>Gastroenterology</i> , Vol. 103:647-651, (1992)	
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	A78	BEDWELL et al., "Fluorescence Distribution And Photodynamic Effect Of ALA-Induced PP IX In The DMH Rat Colonic Tunour Model", <i>Br. J. Cancer</i> , Vol. 65:818-824, (1992)	
	A79	REBEIZ et al., "Photodestruction Of Tumor Cells By Induction Of Endogenous Accumulation Of Protoporphyrin IX: Enhancement By 1, 10-Phenanthroline", <i>Photochemistry and Photobiology</i> , Vol. 55(3):431-435, (1992)	
	A80	ANDREONI et al., "Effects of HpD And Laser On Transformed and Corresponding Normal Cultured Cells: Diiferential Cytotoxicity As An In Vitro Model For Tumor Photochemotherapy", <i>Porphyryns in Tumor Phototherapy</i> , pp.143-155, (1993)	
	A81	ROBINO et al. "Porphyrin Metabolism In Human Neoplastic Tissues", <i>Panminerva Medica</i> , pp. 290-292	
	A82	SAMSOEN M., Arsenal Medicamenteux Dermatologique, Pg. 603-606, ISSN. 0752-5370 (1995) (Abstract)	
	A83	POTTIER et al., "Non-Invasive Technique for Obtaining Fluorescence Excitation and Emission Spectra In Vivo" <i>Photochemistry and Photobiology</i> , Vol. 44, No. 5, pp. 679-687, (1986)	
	A84	N. NAVONE et al., porphyrin biosynthesis in human breast cancer. Preliminary mimetic in vitro studies, <i>Med. Sci. Res.</i> , 1998; 16, 61-62, Buenos Aires, Argentina.	

Examiner Signature	Date Considered
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